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was not written for publication and is not binding
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Paper No.11

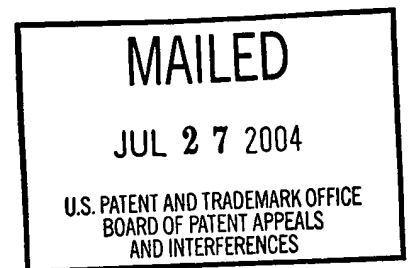
UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte ANTHONY C. ALIBERTO,
SCOTT M. EVANS, and
WILLIAM J. WORTHEN

Appeal No. 2004-1407
Application No. 10/057,334

ON BRIEF



Before METZ, GRON, and HANLON, Administrative Patent Judges.
GRON, Administrative Patent Judge.

DECISION ON APPEAL UNDER 35 U.S.C. § 134

This is an appeal under 35 U.S.C. § 134 from an examiner's
final rejection of Claims 5 and 8, which are all the claims

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pending in U.S. Application No. 10/057,334, filed January 23,
2002.

Introduction

Claim 5 stands finally rejected under 35 U.S.C. § 103(a) as being unpatentable over the combined teachings of Ginsburg, U.S. Patent No. 5,486,208, issued on January 23, 1996; and Clifton, U.S. Patent No. 5,486,204, issued on January 23, 1996. Claim 8 stands finally rejected under 35 U.S.C. § 103(a) as being unpatentable over the combined teachings of Dato, U.S. Patent No. 3,425,419, issued on February 4, 1969; and Williamson, IV et al. (Williamson), U.S. Patent No. 5,716,370, issued on February 10, 1998. Claims 5 and 8 read as follows:

5. A method for treating a human patient, comprising the acts of: advancing a heat exchange catheter device into the patient; circulating coolant through the catheter device while preventing infusion of the coolant directly into the patient's bloodstream, the catheter device including at least one heat exchange region; and performing aneurysm surgery while the patient's temperature is below normal body temperature.

8. A method for treating a human patient, comprising the acts of: advancing a heat exchange catheter device into the patient; circulating coolant through the catheter device while preventing infusion of the coolant directly into the patient's bloodstream, the catheter device including at least one heat exchange region; and performing minimally invasive heart surgery on the patient while the patient's temperature is below normal body temperature.

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We have considered the applicants' specification and claims, the applied prior art, and the positions of the examiner and appellant set forth in the examiner's answer and appellant's brief respectively. We conclude that the prior art teaching establishes a prima facie case of obviousness under 35 U.S.C. § 103(a) for the invention defined by Claims 5 and 8. Appellant has presented no objective evidence of nonobviousness. Accordingly, we affirm the examiner's final rejections.

Discussion

"The PTO has the burden under section 103 to establish a prima facie case of obviousness." In re Fine, 837 F.2d 1071, 1073, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988). Claims 5 and 8 comprise the step of treating a human patient by heat exchange cooling using a commonly defined catheter device. Claim 5 is directed to a method for treating a human patient while performing aneurysm surgery. Claim 8 differs from Claim 5 in that it is drawn to a method for treating a human patient while performing minimally invasive heart surgery.

The examiner relies on the combined teachings of Ginsburg and Clifton, and Dato and Williamson, as evidence that the claimed inventions would have been obvious to one of ordinary skill in the art at the time the inventions were made. Ginsburg describes a method for cooling a patient by heat exchange using a

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catheter device. (Ginsburg, column 2, line 65, to column 3, line 10). Ginsburg teaches that it is beneficial to cool a patient during surgery, because cooling the body lowers its oxygen requirements. (Ginsburg, column 2, lines 47-52). Dato discloses a method for cooling a patient during heart surgery by heat exchange using a catheter device. (Dato, column 5, lines 51-54).

Clifton and Williamson both describe types of surgery where cooling a patient is beneficial. Clifton teaches that hypothermia is useful during aneurysm surgery. (Clifton, column 1, lines 25-36). Williamson teaches that hypothermia is useful during heart surgery. (Williamson, column 2, lines 1-7). Williamson also discloses a minimally invasive procedure used to repair a heart valve. (Williamson, column 6, lines 36-39 and 62-65).

The original claims of the application before us were directed to methods for use in a variety of surgical procedures. Applicants in this case subsequently limited their claims to aneurysm and minimally invasive heart surgeries. However, neither the specification before us nor the prior art suggest that there are patentable distinctions when using a heat exchange cooling catheter during different types of surgeries. Appellants do not argue that the device used in the claimed method is either novel or unobvious.

"During patent examination the pending claims must be interpreted as broadly as their terms reasonably allow." In re Zletz, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1988). Neither aneurysm surgery nor minimally invasive heart surgery is defined in applicants' specification. On the other hand, "aneurysm" is broadly defined in Stedman's Medical Dictionary¹ as follows:

Circumscribed dilation of an artery, or a blood-containing tumor connecting directly with the lumen of an artery.

It appears from the above definition that a surgeon generally performs aneurysm surgery on arteries of the body. Furthermore, minimally invasive heart surgery may encompass many types of heart surgeries depending on one's definition of minimally invasive. We conclude that minimally invasive heart surgery and aneurysm surgery generally encompass a broad scope of surgeries.

In our view, persons having ordinary skill in the art would have understood Ginsburg and Dato as disclosing methods for cooling a patient using a catheter generally during surgery and touting the benefits thereof. One of ordinary skill in the art would have further recognized that cooling a patient is beneficial during aneurysm surgery and minimally invasive heart

¹Stedman's Medical Dictionary, 24th ed., p.71 (Williams & Wilkins, Baltimore, MD 1982). See Appendix.

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surgery in view of the teachings in Clifton and Williamson. Therefore, it would have been prima facie obvious at the time the claimed invention was made to cool a patient by heat exchange using a catheter device as disclosed in Ginsburg and Dato during aneurysm surgery as well as minimally invasive heart surgery.

Appellants' arguments do not undermine the established prima facie case of obviousness. Appellants argue there is little expectation of success in applying Ginsburg's teaching to particular types of surgery. (Appeal Brief, page 3, third full paragraph). Appellants' argument is unpersuasive. Applicants' specification does not now, and never did, limit the invention disclosed to any particular type of surgery. Moreover, Ginsburg recognizes the beneficial effects of cooling a patient during surgery. To the extent appellants are questioning the efficacy of cooling a patient as described in Ginsburg during aneurysm surgery, all that is required for obviousness under 35 U.S.C. § 103(a) is a "reasonable expectation of success." In re O'Farrell, 853 F.2d 894, 904, 7 USPQ2d 1673, 1681 (Fed. Cir. 1988). The examiner relies on the combined teachings of Ginsburg and Clifton as evidence of such a "reasonable expectation of success."

Appellants further argue that there is no motivation to combine references because Clifton teaches profound hypothermia

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during aneurysm surgery, and Ginsburg's catheter cannot create profound hypothermia. (Appeal Brief, page 4, second paragraph). This argument is also unpersuasive. Applicants' claimed methods are not limited to, and do not distinguish between, degrees of cooling.

Finally, appellants argue that Dato does not teach a minimally invasive approach and there is no expectation that Dato could be used in a minimally invasive approach. (Appeal Brief, page 4, second paragraph). Appellants do not explain why a procedure useful for invasive heart surgery generally would be inappropriate during minimally invasive heart surgery. If a person having ordinary skill in the art may use Dato's approach during a complicated thoracotomy wherein Dato requires insertion of the catheter through the femoral vein, it would appear that Dato's approach would also be suitable for less invasive heart surgical procedures.


Conclusion


For the reasons stated above, we affirm the examiner's final rejections of Claims 5 and 8 of Application No. 10/057,334 under 35 U.S.C. § 103(a).

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No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136 (a).

AFFIRMED


ANDREW H. METZ
Administrative Patent Judge


TEDDY S. GRON
Administrative Patent Judge

BOARD OF PATENT
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INTERFERENCES


ADRIENE LEPIANE HANLON
Administrative Patent Judge

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APPENDIX

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Stedman's
MEDICAL
DICTIONARY
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WILLIAMS & WILKINS
Baltimore/London

anesthesia

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aneurysm

rectal a., general a. following instillation into the rectum of liquid inhalation anesthetics or intravenous anesthetics.
refrigeration a., cryoanesthesia.
regional a., use of local anesthetic solution(s) to produce circumscribed areas of loss of sensation; a generic term, regional a. includes conduction, nerve block, spinal, epidural, field block, infiltration, and topical a.
retrobulbar a., injection of a local anesthetic behind the eye to produce sensory denervation of the eye.
sacral a., regional a. limited to those areas innervated by sacral sensory nerves.
saddle block a., a form of spinal a. limited in area to the buttocks, perineum, and inner surfaces of the thighs.
segmental a., loss of sensation limited to an area supplied by one or more spinal nerve roots.
semi-closed a., inhalation a. using a circuit in which a portion of the exhaled air is exhausted from the circuit and a portion is rebreathed following absorption of carbon dioxide.
semi-open a., inhalation a. in which a portion of inhaled gases is derived from an anesthesia circuit while the remainder consists of room air.
spinal a., (1) subarachnoid a.; sensory denervation produced by injection of local anesthetic solution(s) into the spinal subarachnoid space; (2) loss of sensation produced by disease of the spinal cord.
splanchnic a., visceral a.; loss of sensation in those areas of the visceral peritoneum innervated by the splanchnic nerves.
stocking a., loss of sensation in the area covered by a stocking.
subarachnoid a., spinal a. (1).
surgical a., (1) any a. administered for the purpose of permitting performance of an operative procedure, as differentiated from obstetrical, diagnostic, and therapeutic a.; (2) loss of sensation with muscle relaxation adequate for operation.
tactile a., loss or impairment of the sense of touch.
therapeutic a., administration of an anesthetic as a means of treatment; e.g. for asthma or causalgia.
thermal or thermic a., loss of heat sense.
to-and-fro a., a. by means of a valveless closed a. circuit in which respired gases pass back and forth through a carbon dioxide absorbent interposed between patient and respiratory reservoir bag.
topical a., surface analgesia; superficial loss of sensation in mucous membranes or skin, produced by direct application of local anesthetic solutions, ointments, or jellies.
total spinal a., spinal a. extensive enough to produce loss of sensation in all extracranial sensory roots.
traumatic a., loss of sensation resulting from nerve injury.
unilateral a., hemianesthesia.
visceral a., splanchnic a.

anesthesiologist. A physician specializing solely in anesthesiology and related areas (to be differentiated from anesthetist, q.v.).

anesthesiology (an'es-the-zī-ol'ō-jī) [anesthesia + G. *logos*, treatise]. The medical specialty concerned with the pharmacological, physiological, and clinical basis of anesthesia and related fields, including resuscitation, intensive respiratory care, and pain.

anesthesiophore (an'es-the-zī-ō-fōr) [anesthesia + G. *phoros*, bearing]. The active group of a molecule that confers anesthetic or hypnotic effect.

anesthetic. 1. Anesthetic agent; a compound (e.g., ether) that reversibly depresses neuronal function, producing loss of ability to perceive pain and/or other sensations. 2. Collective designation for anesthetizing agents administered to an individual subject at a particular time. 3. Characterized by loss of sensation or capable of producing loss of sensation. 4. Associated with or due to the state of anesthesia.

flammable a., an a. agent that supports combustion and forms explosive mixtures with air or oxygen.

general a., a compound that produces loss of sensation and loss of consciousness.

inhalation a., a gas or a liquid with a vapor pressure great enough to produce general anesthesia when breathed.

intravenous a., a compound that produces anesthesia when injected into the circulation via venipuncture.

local a., a compound that, when applied directly to mucous membranes or when injected about nerves, produces loss of sensation by inhibiting nerve excitation or conduction.

primary a., the compound that contributes most to loss of sensation when a mixture of anesthetics is administered.

secondary a., a compound that contributes to, but is not primarily responsible for, loss of sensation when two or more anesthetics are simultaneously administered.

spinal a., (1) a local anesthetic agent capable of producing loss of sensation when injected into the subarachnoid space; (2) the provision of anesthesia by the subarachnoid injection of a local anesthetic (he had a spinal anesthetic for his operation).

volatile a., a liquid a. drug that volatilizes to a vapor; when the vapor is inhaled, general anesthesia is produced. See also anesthetic vapor.

anesthetist. The person who administers an anesthetic, whether an anesthesiologist, a physician who is not an anesthesiologist, a nurse anesthetist, etc.

anesthetization. The act of producing loss of sensation.

anesthetize. To produce loss of sensation.

aneurous (an-es'trus). Relating to the anestrus.

anestrus (an-es'trus) [G. *an-* priv. + *oistros*, a gadfly, mad desire (estrus). EST-]. The period of sexual quiescence between the estrus cycles of mammals; may be (a) a prolonged period in monestrous animals (dogs) or seasonally polyestrous animals (sheep), or (b) a prolonged period of failure of estrus in mature nonpregnant, polyestrous animals.

anethole (an'e-thōl). Anise camphor; 1-methoxy-4-propenylbenzene; *p*-propenylanisole; a derivative of fennel and anise oils; a flavoring substance.

anethopath [G. *an-* priv. + *ethos*, custom, + *pathos*, suffering]. A morally uninhibited person.

anetoderma (an-e-to-der'mah) [G. *anetos*, relaxed (ES-), + *derma*, skin]. Primary idiopathic macular atrophy; atrophía maculosa varioliformis cutis; an unusual form of atrophoderma characterized by circumscribed translucent lesions in which the skin becomes baglike and wrinkled. **Jadassohn-Pellizzari a.**, atrophy preceded by erythema or urticaria.

Schweninger-Buzzi a., atrophy with no preceding inflammation.

aneuploid (an'u-ploid) [G. *an-* priv. + *euploid*]. Having an abnormal number of chromosomes not an exact multiple of the haploid number.

aneuploidy. State of having an abnormal number of chromosomes not an exact multiple of the haploid number.

partial a., a type of mosaicism in which some cells have a normal number of chromosomes and some have an abnormal number.

aneuria (ā-nū'rī-ah) [G. *an-* priv. + *neuron*, nerve]. Lack of nervous energy. See also neurasthenia.

aneuric. Relating to or affected by aneuria.

aneurine (an'u-rēn). Thiamin: a. hydrochloride, *thiamin hydrochloride*.

aneurolemmic (ā-nū-ro-lēm'ik). Without a neurolemma.

aneurysm (an'u-rizm) [G. *aneurysma* (-mat-), a dilation, fr. *eurys* wide]. Circumscribed dilation of an artery, or a blood-containing tumor connecting directly with the lumen of an artery.

ampullary a., saccular a.

a. by anastomosis, a mass of dilated anastomosing vessels that produce a pulsating tumor usually in a superficial position.

arteriosclerotic a., atherosclerotic a.; the commonest type of a. occurring in the abdominal aorta and other large arteries in the elderly; due to weakening of the media by severe atherosclerosis.

arteriovenous a., a dilated arteriovenous shunt.

atherosclerotic a., arteriosclerotic a.

axial a., an a. involving the entire circumference of a blood vessel.

bacterial a., one caused by the growth of bacteria within the vascular wall, usually following impaction of a septic embolus.